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Title:

MULTILAYERED BIODEGRADABLE STENT AND METHOD FOR ITS MANUFACTURE. ;

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Equivalents: CA2111455, JP6218063

ABSTRACT:

A stent (12) of multilayered luminated construction wherein one layer (18) addresses the structural requirements of the stent and additional layers (20,22) release drugs at predictable rates. Both the structural layer (18) as well as the drug releasing layers (20,22) are eventually completely resorbed by the body.

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(54) **Multilayered biodegradable stent and method for its manufacture.**

(57) A stent (12) of multilayered luminated construction wherein one layer (18) addresses the structural requirements of the stent and additional layers (20,22) release drugs at predictable rates. Both the structural layer (18) as well as the drug releasing layers (20,22) are eventually completely resorbed by the body.

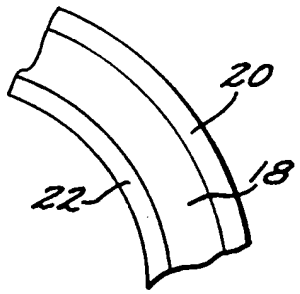


FIG. 2

EP 0 604 022 A1

The present invention relates to expandable intraluminal vascular grafts, generally referred to as stents. More particularly, the invention pertains to stents that are biodegradable and capable of releasing therapeutic drugs.

Stents are implanted within lumens of vessels of the body in order to maintain the patency of such vessels. A variety of delivery systems have been devised that facilitate the placement and deployment of stents. The stent initially is manipulated while in its contracted state, wherein its reduced diameter more readily allows it to be introduced into the lumen and maneuvered into place. Once in place, it is enlarged to a diameter either greater than or equal to the diameter of the lumen so as to allow the free flow of fluids therethrough.

A system especially adapted for coronary applications employs a stent design that incorporates a combination of interacting elements which serve to automatically lock the stent into its enlarged configuration upon expansion. The stent is moved into position along a guidewire that previously has been placed in the lumen where the stent is to be deployed. Inflation of a balloon about which the stent rests causes the stent to expand and lock. Subsequent deflation of the balloon and withdrawal of the catheter and guidewire leaves the stent in place. Elements extending from the surface of the stent engage the vessel walls to positively maintain the stent in position within the lumen.

Stents heretofore typically have been formed of non-toxic, substantially biocompatible metals such as stainless steel, tantalum, or gold. However, it has been determined that typically within about seven to twenty-one days the endothelial layer of the artery or vessel grows into and throughout the walls of the stent, at which point the utility of the stent substantially is diminished and the continued presence of the stent in the lumen may cause any of a variety of problems or complications. Therefore, it has been proposed to form stents of biodegradable or bioabsorbable materials that are completely resorbed by the body within a period of time.

Continued pharmacological treatment of the vessel or condition that made the implantation of the stent necessary often is required or desirable. Such treatment typically is most effective when administered locally and, as a result, it has been suggested to rely on the stent for the delivery of drugs to provide this treatment. Materials are known that are capable of absorbing certain drugs and subsequently releasing the drugs at a substantially predictable rate for a proscribable period of time under particular environmental conditions. By forming the stent of such drug-impregnated material or by otherwise associating such material with the stent, the stent can achieve the dual purpose of maintaining patency and of dispensing drugs.

The prior art has been unable to provide a stent that is completely absorbed by the body after deployment, possesses the physical properties necessary to facilitate its implantation, performs a primary function of maintaining the patency of the vessel for a period of time, and gradually releases a drug prior to its resorption. Previous attempts to impart the necessary physical properties to drug-releasing materials or attempts to impart such properties to those materials without compromising the drug-releasing properties or the efficacy of the drugs absorbed have been unsuccessful.

The present invention provides a stent that is both completely resorbable by the body and capable of delivering certain drugs. Moreover, the stent possesses all the physical properties necessary for it to perform its structural function as well as to facilitate its implantation. This is achieved by employing a multilayered, laminated construction. A first bioabsorbable layer is selected for its physical properties. One or more additional resorbable layers are selected for the ability of the layer or layers to retain various drugs and then gradually release the drugs upon exposure to the particular environment to which the stent is exposed to upon implantation.

The laminated construction allows the combination in a single stent of a plurality of different drug containing materials. By appropriate configuration of the layers, drugs can be either delivered simultaneously with deployment of the stent or released in a predetermined and controlled sequence. Moreover, different parts of the anatomy can be targeted for treatment using different drugs. That is, a drug-containing layer which is associated only with the exterior surface of the stent would cause that drug to be released directly into the vessel wall while a drug-containing layer associated only with the interior surface of the stent would cause the drug to be released into, and to free flow within, the lumen.

The laminated construction of the stent allows the structural layer to be fabricated before it is laminated. Therefore, any layer can be subjected to rigorous conditioning during its processing and treatment that might be advantageous in order to impart sufficient strength to the layer or layers. In the case of prior art stents, this rigorous conditioning might have the effect of deteriorating or causing a degradation in the effect of any drug or drug-releasing materials. The present invention provides for the drug-impregnated materials to be combined with the structural layer only after the fabrication of the structured layer is complete.

The material selected for the structural layer of the stent of the present invention must be reabsorbable while providing the necessary physical char-

acteristics. These requirements can be satisfied by using polymers such as poly-L-lactic acid or polyglycolic acid that have been extruded and oriented to obtain maximum tensile strength and optimal flexural properties.

The drug-releasing layers are selected based on the properties of the materials used to retain sufficient quantities of particular drugs, to release those drugs at a constant or at least predictable rate when exposed to the environment encountered upon implantation, and to eventually become completely absorbed by the body. Polymers capable of such functions include poly-DL-lactic acid or polycaprolactone. Such polymers are first intermixed with the drug or drugs to be delivered and then are either extruded or solvent cast. The drug-containing layer or layers and the structural layer subsequently are laminated to one another using heat or solvents.

The present invention advantageously is applied to stents implantable in a coronary artery after an angioplasty procedure has been performed wherein the exterior surface of the stent releases a drug into the vessel wall that tends to discourage restenosis and also discourages coagulation of the fluid passing through the lumen. Alternatively, a stent according to the present invention may be utilized to treat prostate cancer. In this application, a chemotherapeutic drug is released directly into the urethra via the implanted stent.

These and other features and advantages of the present invention will become apparent from the following detailed description of the preferred embodiments which, taken in conjunction with the accompanying drawings, illustrates by way of example the principles of the invention.

In the drawings:

Figure 1 is a perspective view of a stent of the present invention; and

Figure 2 is an enlarged cross sectional view showing the laminated construction of the stent of Figure 1.

The Figures illustrate a preferred embodiment of the present invention. Generally, Figure 1 illustrates stent 12 prior to implantation. The stent is formed as a furled cylinder of sufficiently small outer diameter so as to be transportable through the lumen in which it is to be deployed and of sufficiently large internal diameter to receive a balloon catheter therein. The tabs 14 extending from the outer surface of the catheter are sized to engage apertures 16 after the balloon has been inflated. The process of inflating the balloon causes the cylinder to unfurl and thereby expand. Once elements 14 and 16 have engaged, the stent effectively is locked into its expanded state and cannot recontract.

Figure 2 is an enlarged crosssectional view of the stent 12 according to the present invention. The stent comprises a laminated structure comprising multiple layers. The particular embodiment illustrated has three layers, layers 18, 20, and 22. Central, relatively thick layer 18 comprises the structural component of the stent which imparts the necessary physical characteristics to make the stent capable of maintaining the patency of a lumen. This central layer also imparts the desired flexural characteristics to the stent to allow it to be positioned as well as to be expanded once positioned. Thinner layers on either side of structural layer 18 deliver pharmacological agents. Materials that form the thinner layers are selected for the ability of the materials to absorb drugs and subsequently release the drugs at predictable rates once the stent is subjected to the environment encountered upon implantation. In the embodiment illustrated, the layers are disposed such that each is adjacent a surface of central structural layer 18. These layers may contain the same type of drug or different drugs. Alternatively, only one drug-releasing layer might be laminated to one surface of the stent. In still another aspect, additional drug-releasing layers can be built up on top of one another to allow sequential release of various medicaments.

The material employed for the structural layer is selected based on the ability of the material to impart the necessary physical properties to the stent as well for its capacity to be completely reabsorbed by the body. "Resorbable" is meant to encompass all those materials that are either biodegradable, bioerodable, or bioabsorbable and includes materials that break down over time and are gradually absorbed or those that are eliminated by the body regardless of whether the degradation mainly is due to hydrolysis or is mediated by metabolic processes. As previously mentioned, the strength of such material must be such that once the stent is in its expanded and locked form, it is capable of maintaining the patency of the vessel into which it is implanted. Additionally, the physical characteristics of the material of the structural layer must be such as to provide flexibility sufficient to allow it to be expanded by, for example, the inflation of a balloon contained therein. Furthermore, a degree of longitudinal flexibility is desirable in order to facilitate transportation of the stent through a potentially tortuous path through the lumen to its intended implantation site.

Materials with the capacity to provide both the structural integrity and resorbability required being resorbable typically are polymeric in nature. Polymers such as poly-L-lactic acid or polyglycolic acid which have been extruded and oriented by known methods to obtain maximum tensile strength as well as optimal flexural properties are well-suited

for such application. Polyorthoesters or polyanhydrides also could be used. In the present invention, the laminated construction of the stent allows the structural layer to be processed and treated to enhance its physical properties without concern for the effect such potentially rigorous conditions would have on drug and drug-containing materials.

The materials used for drug-releasing layers 20 and 22 are selected for the ability to be absorbed and the ability to retain various drugs and subsequently release the medicaments at a predictable rate upon implantation of the stent. Materials found to be especially advantageous for such purposes include polymers such as poly-DL-lactic acid and polycaprolactone. These polymers can be intermixed with the drug or drugs to be released and subsequently extruded or solvent cast by well-known methods.

After the central structural layer and any drug-releasing layers have been fabricated, the layers are laminated to one another using heat or solvents. For example, a layer of poly-L-lactic acid and a poly-DL-lactic acid are combinable by configuring the two layers in intimate contact and subjecting the layers to a temperature of about 55 °C. The completed laminate subsequently is stamped or laser-cut to the appropriate dimensions. The elements and features necessary to initially maintain the stent in a furled state and subsequently allow it to be locked into its expanded state are formed by similarly well known methods. A final furling or shaping operation renders the stent substantially ready for use.

The ultimate purpose of the stent dictates the dimensions of the stent, the strength requirements and physical characteristics of the stent, and the particular drugs and drug delivery rates selected. For example, when the goal is to maintain the patency of a coronary artery, a stent according to the present invention wherein the innermost layer exposed to the lumen is configured to release a drug that reduces the likelihood of thrombosis. Heparin or prostacyclin are among the drugs appropriate for this purpose. In such an application, outer layer 20 could advantageously release drugs that address restenosis. Drugs that have been found to be effective for this purpose include angiopeptin, methotrexate, and heparin.

While a particular form of the invention has been illustrated and described, it also will be apparent to those skilled in the art that various modifications can be made without departing from the spirit and scope of the invention. Any of a variety of stent designs and applications can benefit from the present invention. Accordingly, it is not intended that the invention be limited except by the appended claims.

Claims

1. An expandable intraluminal stent for implantation in a vessel, comprising:

   a first layer formed of resorbable material selected to impart structural rigidity to said stent; and

   a second layer of a resorbable material, joined to said first layer and selected to release a therapeutic drug at a selected rate therefrom, whereby upon implantation, said stent initially provides a desired degree of structural support to said vessel, releases said drug at the selected rate and eventually is completely resorbed.

2. A stent as claimed in claim 1, wherein said first layer is further selected to impart additional desired physical characteristics to said stent.

3. A stent as claimed in claim 1, wherein said first layer comprises poly-L-lactic acid, or polyglycolic acid.

4. A stent as claimed in any one of claims 1 to 3, wherein said second layer comprises poly-DL-lactic acid or polycaprolactone.

5. A stent as claimed in any one of the preceding claims wherein said stent is implantable in a lumen upstream from a cancerous growth and said second layer is selected to release a chemotherapeutic drug.

6. A stent as claimed in any one of the preceding claims wherein said second layer is selected to release heparin.

7. A stent as claimed in any one of the preceding claims wherein a third layer of resorbable material is joined to said first layer and selected to release a therapeutic drug at a selected rate therefrom, whereby upon implantation, said stent initially provides a desired degree of structural support to said vessel, releases said drugs at the selected rates and eventually is completely resorbed.

8. A stent as claimed in claim 7, wherein the drugs released by said first and second layer are identical.

9. A stent as claimed in claim 7, wherein the drugs released by said first and second layer are different.

10. A stent as claimed in claim 9, wherein said stent is implantable within a coronary artery,

said second layer is joined to the outer side of said stent's first layer and releases a drug that addresses restenosis and said third layer is joined to the inner side of said stent's first layer and releases a drug that addresses thrombosis.

11. A stent as claimed in claim 7, wherein said second layer is selected to release angiopeptin and said third layer is selected to release heparin.

12. A method of fabricating a biodegradable, drug releasing stent for implantation within a lumen, comprising the steps of:

forming a first layer of biodegradable material having physical properties necessary to enable a stent to perform its structural function within said lumen;

forming a second layer of biodegradable material which releases a selected drug upon exposure to an environment such as is encountered within said lumen; and

joining said second layer to said first layer to provide a laminated structure that is biodegradable, drug releasing and has the physical properties necessary for said stent to perform its structural function within said lumen.

13. A method as claimed in claim 12, further comprising the steps of:

forming a third layer of biodegradable material which releases a selected drug upon exposure to an environment such as is encountered within said lumen; and

joining said third layer to said first layer.

14. A method as claimed in claim 12 or claim 13, wherein said first layer is formed by extrusion and orientation of a polymeric material.

15. A method as claimed in claim 14, wherein said polymeric material comprises poly-L-lactic acid or polyglycolic acid.

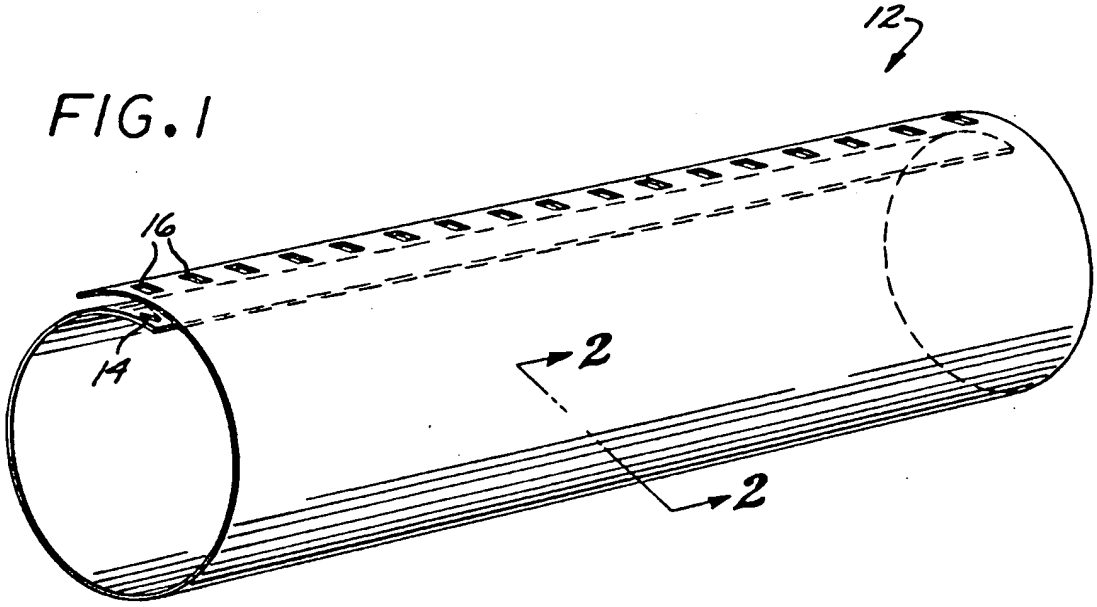
16. A method as claimed in any one of claims 12 to 15, wherein said second layer comprises a mixture of said drug and a polymeric material.

17. A method as claimed in claim 16, wherein said polymeric material comprises poly-DL-lactic acid or a polycaprolactone.

18. A method as claimed in any one of claims 12 to 17, wherein said second layer is joined to said first layer with the application of heat or with the use of solvents.

19. A method as claimed in any one of claims 13 to 17, wherein said second and third layers are joined to said first layer with the application of heat or with the use of solvents.

FIG. 1



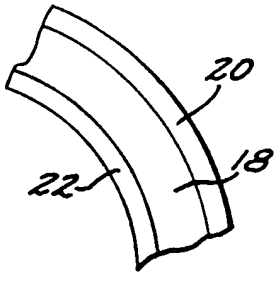


FIG. 2

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 30 9386

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X	WO-A-90 01969 (M-J. SLEPIAN)	1-9,12, 13,16-19	A61F2/06 A61L31/00
Y	* page 10, line 27 - page 14, line 5; figures 1-8 * * page 24, line 26 - line 31 * ---	10,11, 14,15	
Y	WO-A-91 17744 (G.R. JERNBERG)	10,11	
A	* page 6, line 32 - page 7, line 21 * * page 9, line 3 - line 16 * * page 10, line 2 - line 29; claims 9,18,22,35,36; figures 4A-4D * ---	1-4,6-9	
Y	WO-A-90 04982 (BIOCON)	14,15	
A	* abstract * * page 16, line 26 - page 17, line 6; table 1 * ---	1-5	
X	WO-A-91 17789 (R.S. STACK ET AL.)	1-3,6, 12,16	
	* page 17, line 32 - line 36 * * page 21, line 18 - page 22, line 11 * * page 23, line 12 - line 16 * ---		TECHNICAL FIELDS SEARCHED (Int.Cl.5)
A	EP-A-0 364 787 (EXPANDABLE GRAFTS PARTNERSHIP) * column 12, line 48 - line 57; figures 5,6 * ---	1,4,12	A61F A61L A61M
A	US-A-5 100 429 (E.L. SINOVSKY ET AL.)	1-3, 12-19	
	* column 8, line 43 - line 52; figures 6,7 * * column 9, line 37 - line 66 * ---		
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	28 February 1994	Wolf, C

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 30 9386

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
A	WO-A-92 10218 (W.L. GORE & ASSOCIATES) * page 7, line 8 - line 34; figures 2,4,12 * * page 9, line 19 - line 27 * * page 12, line 24 - line 31 *	1-10,12, 13,15, 16,18,19	
A	WO-A-90 06094 (BRIGHAM AND WOMEN'S HOSPITAL) * page 9, line 22 - line 26 * * page 14, line 15 - page 15, line 25 *	1,2, 5-13,16, 18,19	
A	EP-A-0 493 788 (MUDR. MILAN KRAJICEK CSC.) * column 2, line 12 - column 3, line 9; figure *	7-11	
A	WO-A-89 03232 (BUKH MEDITEC) * abstract; claims 4,7,16 *	1-5, 12-16, 18,19	TECHNICAL FIELDS SEARCHED (Int.Cl.5)
P,X	WO-A-93 06792 (SCIMED LIFE SYSTEMS) * abstract * * page 12, line 5 - page 13, line 2 * * page 18, line 24 - line 30 * * page 19, line 24 - page 21, line 17 * * page 22, line 10 - page 23, line 2 *	1-19	

The present search report has been drawn up for all claims

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L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

Requested Patent: EP0621015A1

Title:

STENT WITH A COVERING LAYER OF ELASTIC MATERIAL AND METHODS FOR APPLYING THE LAYER ON THE STENT. ;

Abstracted Patent: EP0621015 ;

Publication Date: 1994-10-26 ;

Inventor(s): LUKIC GORAN (CH) ;

Applicant(s): SCHNEIDER EUROP AG (CH) ;

Application Number: EP19930106646 19930423 ;

Priority Number(s): EP19930106646 19930423 ;

IPC Classification: A61F2/06 ;

Equivalents:

CA2114891, CA2205533, CA2206709, CA2206712, DE69317548D, DE69317548T, ES2114964T, JP2914420B2, JP7000529

ABSTRACT:

The stent comprises a cylindrical wall (1) formed by meshed wires (2) and a covering layer (3) of elastic material extending on a portion of its length, with an outer surface (4), and totally embracing the wire mesh.

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(51) Int. Cl.[5]: **A61F 2/06**

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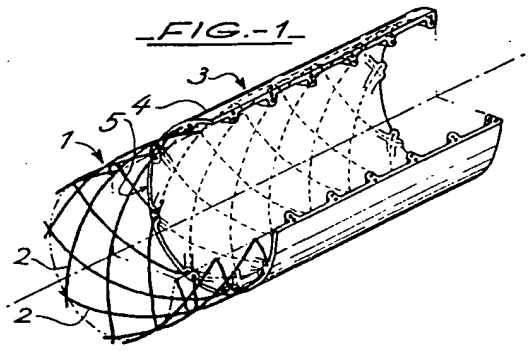
(54) Stent with a covering layer of elastic material and methods for applying the layer on the stent.

(57) The stent comprises a cylindrical wall (1) formed by meshed wires (2) and a covering layer (3) of elastic material extending on a portion of its length, with an outer surface (4), and totally embracing the wire mesh.

FIG.-1-



EP 0 621 015 A1

This invention relates to a stent with a discontinuous expandable wall comprising on at least a portion of its length a continuous covering layer of elastic material with an outer surface surrounding the discontinuous wall. This invention also relates to methods for applying such a layer on a stent.

The discontinuous walls of stents, such as for instance the macroporous walls formed by a deformable wire mesh allowing diametral retraction for introduction of the stent into air or food pipes and expansion therein for dilatation, or repair, or bridging of said pipes, have the disadvantage that they permit ingrowth of tumors and other rapid growth cells through the wire mesh or discontinuous wall, with the resulting risk of stent occlusion.

For preventing ingrowth of cells through the stent, the document DE-3918736-A1 describes an expandable metallic stent with an inner teflon tube affixed to the stent by suture or pressure, or an inner tube and an outer tube, both of teflon, connected pouch like to each other. At least in case of degradation of the inner tube, there will be a strong risk of having flaps from the inner tube occluding the vessel, or migration of the inner tube with respect to the stent and a further risk of occlusion of the vessel. Furthermore, the absence of resiliency of teflon does not allow constriction and expansion of the stent without additional place consuming measures such as zig-zag folds of the teflon tubes.

The document "Endoscopy 1992 : 416-420" also describes an expandable metallic stent for preventing ingrowth of malignant structures. This stent, formed by an expandable wire mesh, is covered by a silicone membrane or skirt which surrounds a portion of its length.

This membrane or skirt is secured around the stent by suture of its ends to the wire mesh, and, in situ, the membrane is thus radially held in place between the stent wall and vessel wall. To have the membrane or skirt positioned between the stent wall and vessel wall is advantageous in case of degradation of the membrane. However, such a coverage of the stent is far from being effortless and mostly will have to be done by hand, which will require skills. In addition, it is limited to certain types of materials and it may prove fragile, being possible to have the membrane or skirt getting loose from the wire mesh, which may allow relative movement between the membrane and the stent, with the resulting risk of occluding the vessel.

The object of this invention is to avoid the aforesaid drawbacks.

To this effect, the stent and methods in accordance with the invention comply with the definitions given in the claims.

In that way, the continuous covering layer is closely bound to the discontinuous structure which it covers and there is definitely no risk of separation therebetween. And even in the case of a strong degradation of the covering layer in course of time, there cannot be any migration of the covering layer with respect to the discontinuous wall of the stent because of the aforesaid intimal interconnection. Furthermore, the liaison of the covering layer with the discontinuous wall of the stent eliminates any delicate, time and skill consuming efforts and allows coating of any kind of discontinuous expandable stent wall.

The invention will now be described more particularly with reference to the accompanying drawings which show, by way of example only, one embodiment of the invention.

In the drawings :

Figure 1 is a perspective view of a quarter cut along the longitudinal axis of the exemplified embodiment;

Figure 2 is an enlarged view of an axial cut of a portion of its wall during a procedure for applying the covering layer.

The stent shown in Figure 1 is an expandable stent of which the wall (1), for instance cylindrical, is formed by meshed wires (2) of stainless steel, plastics or hybrid materials such as plastics and carbon fiber.

The wall (1) comprises, on a portion of its length, a covering layer (3) made of an elastomeric biocompatible composition such as, for instance, the elastomeric polymerisable composition described in US Patent N° 5,112,900. The outer face (4) of layer (3) forms a surrounding surface, and layer (3) extends around and inside the discontinuous structure of the stent in order to totally embrace and intimately unite with any material part of the meshed wires (2) which constitute said discontinuous structure.

On Figure 1, the left front face (5) of the covering layer (3) is shown in an area of wall (1) where the wires (2) do not cross each other; on the contrary, the quarter cut along the longitudinal axis is shown in an area where the wires (2) cross and overlap each other.

A portion of the stent wall (1) is shown on Figure 2 with its covering layer (3), the stent wall (1) being shown in an area where its wires (2) overlap each other, and the stent being inserted in a tube (6) the inner surface of which is coated with a lifting medium (7) as described in detail hereafter in connection with a procedure for applying the covering layer to the stent.

In order to apply the covering layer (3) on the stent, the deformable wall (1) of the stent is radially contracted and the portion thereof which has to be coated is inserted into the tube (6) the inner sur-

face of which has been previously done over with a lifting medium (7) such as for instance "teflon" in order to avoid adherence to the elastomeric composition forming the covering layer (3). The contracted stent is allowed to expand radially in the tube (6) and the assembly of the tube and stent is wetted with the elastomeric polymerisable composition dissolved in a sufficient amount of solvent to permit wet forming of a continuous covering layer around the totality of the discontinuous wall of the stent formed by the wire mesh inside the tube (6). The solvent is evaporated and the elastomeric composition is then polymerised in the tube and the layer covered stent portion is taken out of the tube.

In that way, the shaping and liaison of the covering layer with the discontinuous wall of the stent is obtained automatically by mass polymerisation of the elastomeric composition wholly surrounding the structure of such a wall inside the tube moulding its outer surface.

Of course, the discontinuous wall of the stent may also be covered with the continuous covering layer all over its length, in which case the stent will be fully inserted into the tube for the dip forming process. In addition, the invention is not limited to the embodiment shown, being applicable to any kind of expandable stent having a discontinuous wall.

The thickness of the covering layer may be advantageously selected as a function of the quantity of solvent added to the elastomeric composition, before polymerisation and within the limits of a fluidity sufficient to allow wetting.

As a variant, it is also possible to obtain a greater thickness of the portions of the covering layer which are located at the outside of the discontinuous wall of the stent and between the mesh or elements thereof. To this effect, the tube (6) done over with the lifting medium is first wetted alone with the elastomeric composition previously added with an appropriate amount of solvent. The solvent is evaporated and the stent is then radially contracted for insertion into the tube and the procedure follows as outlined hereinbefore.

According to a variant, not shown, the covering layer of elastic material needs not to integrally embrace the discontinuous structure of the stent, being sufficient that only a part of the thickness of the structure be covered by the elastic material, in case of the example shown in Figure 1, only a radial portion of the wires (2).

According to further variants, also not shown, the elastic covering may be achieved by surface adhesion forces or through use of a binder.

Accordingly, a variant method provides for doing over a roll on surface with a lifting medium and coating said roll on surface with an elastomeric polymerisable composition dissolved in a sufficient amount of solvent to permit contact forming, such an elastomeric composition being, for instance, the composition described in US Patent N° 5,112,900. An appropriate portion of the stent in expanded condition is then rolled on said coated roll on surface; the stent is then withdrawn from the roll on surface, the solvent is allowed to evaporate, and the elastomeric composition adhered to the stent is polymerised.

A further variant method provides for using a covering layer formed of a tube made of an elastomeric polymerisable composition, inserting the contracted stent into the tube, allowing the contracted stent to expand in the tube and vulcanising or similarly welding the surface of contact between the stent and the tube.

Still a further variant method also provides for using a covering layer formed of a tube made of an elastomeric polymerisable composition, coating the inside of the tube with an adhesive medium, inserting the contracted stent into the tube, and allowing the stent to expand radially in the so coated tube and the adhesive medium to cure, to thereby achieve adhesion of the assembly of stent and tube.

As a variant of this method, the inside of the tube may be coated with an elastomeric polymerisable composition dissolved in an amount of solvent permitting contact forming, whereby after expansion of the stent, the solvent is allowed to evaporate and the elastomeric coating adhered by contact to the tube and to the stent is polymerised.

In a further variant the covering layer of elastic material may be adhered to the stent by radial pressure of the stent against the covering layer. In that case, the covering layer may be, for instance, formed of a tube made of an elastomeric composition stretched over the stent in order to allow contraction and expansion thereof. Adhesion of the covering layer to the stent will be achieved by surface adhesion forces with additionnal interpenetration between the covering layer and the stent.

In another variant, also not shown, the covering layer may have a structured surface towards the wall of the stent, whereby adhesion of the covering layer to the stent will be achieved by some engagement of said structured surface into the discontinuous structure of the stent.

Of course, in all these variants, the discontinuous wall of the stent may be covered with the continuous covering layer all over its length or only over a portion thereof.

Claims

1. A stent with a discontinuous expandable wall comprising on at least a portion of its length a continuous covering layer of elastic material with an outer surface surrounding the discontinuous wall, characterized in that the continuous covering layer (3) of elastic material is adhered to the said portion of the discontinuous wall (1) of the stent, being thereby intimately united with said wall portion.

2. A stent according to claim 1, characterized in that the continuous covering layer of elastic material extends at least partly radially within the said portion of the discontinuous wall (1) of the stent.

3. A stent according to claim 1 or claim 2, characterized in that the continuous covering layer (3) of elastic material extends around and inside the said portion of the discontinuous wall (1) of the stent.

4. A stent according to any preceeding claim, characterized in that the continuous covering layer is adhered to the discontinuous wall (1) by means of a binder.

5. A stent according to any preceeding claim, characterized in that the continuous covering layer is heat adhered to the discontinuous wall (1).

6. A stent according to any preceeding claim, characterized in that the continuous covering layer is chemically bonded to the discontinuous wall (1).

7. A stent according to any of claims 2 to 6, characterized in that the continuous covering layer is adhered to the discontinuous wall by radial pressure of the discontinuous wall (1) against the continuous covering layer.

8. A stent according to any of claims 2 to 7, characterized in that the continuous covering layer has a structured surface towards the discontinuous wall (1), and wherein the continuous covering layer is adhered to the discontinuous wall as a result of said structured surface.

9. A method for applying the covering layer of the stent according to any of claims 1 to 8, characterized by the steps of :
   - radially contracting the stent,
   - inserting at least a portion of the contracted stent into a tube the inner surface of which has been previously done over with a lifting medium,
   - allowing the stent to radially expand in the tube,
   - wetting the assembly tube plus stent with an elastomeric polymerisable composition dissolved in a sufficient amount of solvent to permit wet forming,
   - evaporating the solvent,
   - polymerising the elastomeric composition in the tube, and
   - taking the layer covered portion of the stent out of the tube.

10. A method according to claim 9, characterized in that the tube the inner surface of which has been done over with a lifting medium is first wetted alone with the elastomeric composition added with solvent, and wherein the solvent is evaporated before the step of insertion of the stent into the tube.

11. A method for applying the covering layer of the stent according to any of claims 1 to 8, characterized by the steps of :
   - doing over a roll on surface with a lifting medium,
   - coating said roll on surface with an elastomeric polymerisable composition dissolved in a sufficient amount of solvent to permit contact forming,
   - rolling at least a portion of the stent in expanded condition on said coated roll on surface,
   - withdrawing the stent from the roll on surface,
   - evaporating the solvent, and
   - polymerising the elastomeric composition adhered by contact on said portion of the stent.

12. A method for applying the covering layer of the stent according to any of claims 1 to 8, characterized by the steps of :
   - forming a tube of predetermined length with an elastomeric polymerisable composition,
   - radially contracting the stent,
   - inserting into the tube a portion of the stent corresponding to said predetermined length of the tube,
   - allowing the stent to radially expand in the tube, and welding the surfaces of contact between the stent and the tube.

13. A method for applying the covering layer of the stent according to any of claims 1 to 8, characterized by the steps of :

- forming a tube of predetermined length with an elastomeric polymerisable composition,
- coating the inside of the tube with an adhesive medium,
- radially contracting the stent,
- inserting into the tube a portion of the stent corresponding to said predetermined length of the tube,
- allowing the stent to radially expand in the tube, and
- allowing the adhesive medium to cure.

14. A method for applying the covering layer of the stent according to any of claims 1 to 8, characterized by the steps of :
    - forming a tube of predetermined length with an elastomeric polymerisable composition,
    - coating the inside of the tube with an elastomeric polymerisable composition dissolved in a sufficient amount of solvent to permit contact forming,
    - radially contracting the stent,
    - inserting into the tube a portion of the stent corresponding to said predetermined length of the tube,
    - allowing the stent to radially expand in the tube,
    - evaporating the solvent, and
    - polymerising the elastomeric composition adhered by contact to the tube and to the stent.

FIG.-1

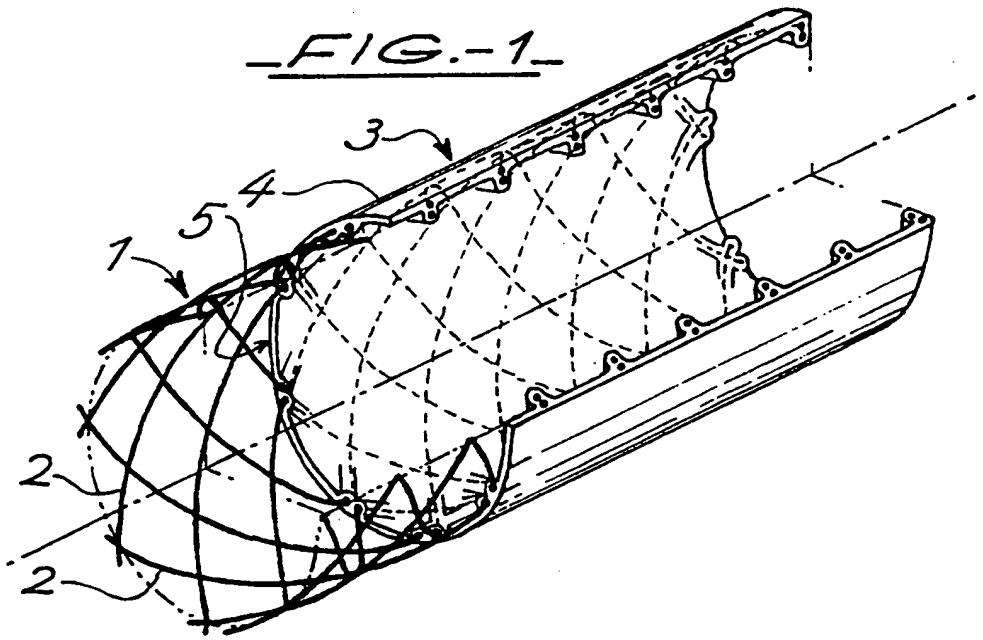
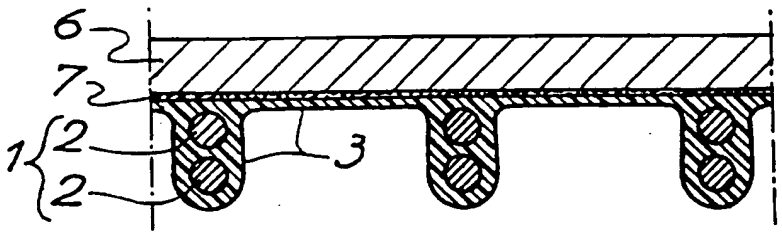


FIG.-2



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EUROPEAN SEARCH REPORT

Application Number
EP 93 10 6646

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X Y	GB-A-1 205 743 (NATIONAL RESEARCH DEVELOPMENT CORPORATION) * page 1, line 53 - line 58; figures 1,4 *	1-3 6	A61F2/06
X Y A	DE-A-4 022 956 (S. FREUDENBERG) * column 4, line 18 - line 42; figures 1,3 * * column 6, line 58 - column 7, line 1 *	1,4 13 2,3,11	
X Y	EP-A-0 435 518 (MED INSTITUTE) * column 5, line 10 - line 18 * * column 6, line 26 - line 28 *	1,2,7 9,10, 12-14	
Y A	US-A-3 879 516 (S. WOLVEK) * column 3, line 62 - column 5, line 16; figures 2-3C * * column 6, line 29 - line 42 *	6,9,10, 14 1-3,12, 13	
Y A	US-A-5 180 376 (R.E. FISCHELL) * column 2, line 26 - line 46; figure 1 *	12 1,2,5,7	TECHNICAL FIELDS SEARCHED (Int. Cl.5)
D,X D,A	DE-A-3 918 736 (C. VALLBRACHT) * column 2, line 10 - line 18; figures 1,2,4 * * column 3, line 1 - line 30; claims 2,4,5 *	1-3,5,7 11	A61F A61M
A	US-A-3 738 365 (R.R. SCHULTE) * column 3, line 3 - line 7; figure 2 *	1,2,7,14	
A	EP-A-0 430 542 (K.K. MACHIDA SEISAKUSHO) * column 5, line 12 - line 17; figure 3 * * column 7, line 23 - line 41; figure 8 *	1,2,7,9, 12-14	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	08 SEPTEMBER 1993	WOLF C.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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